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10/003,850	11/02/2001	Sreekumar Pillai	J6673(C)	6359
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EXAMINER KANTAMNINI, SHOUBHA				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/003,850

Applicant(s)

PILLAI ET AL.

Examiner

Shobha Kantamneni

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 5, 6, 9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) NONE is/are allowed.
- 6) ☒ Claim(s) 1-2, 5-6, 9-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/08/2008 has been entered.

Applicant's amendment filed on 12/08/2008, wherein independent claims 1, and 5 have been amended.

Claims 1, 2, 5-6, and 9-10 are pending, and examined herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Granger et al. (US 5,723,139, PTO-892 of record) and Gorbach (WO 98/56373, PTO-892), in view of Liu et al. (5,976,555, PTO-892 of record), and Soares et al. (US 5,914,116, PTO-1449 of record).

Granger et al. teach a skin conditioning composition comprising a compound selected from retinal or retinyl ester in an amount from about 0.001 % to about 10 %, in combination with a retinoid booster, polycyclic triterpene carboxylic acid, glycyrrhetic acid in an amount from about 0.0001 % to about 50%. See column 1, line 42-column 3, line 39. It is further taught that the combination of retinal or a retinyl ester with a polycyclic triterpene carboxylic acid, glycyrrhetic results in synergistic inhibition of keratinocyte differentiation. Retinoid boosters such as linoleic acid, arachidonic acid etc. are also disclosed as optional ingredients in the composition. See column 4, lines 29-38. The composition is applied to the skin for treating a skin conditions such as dry skin, photodamaged skin, appearance of wrinkles, age spots, acne, skin lightening etc. See column 12, claims 1-6. Granger et al. further disclose that the skin care composition therein is stored in a suitable container to form a skin care product. See column 11, EXAMPLE 6-7.

Granger et al. do not specifically teach the presence of phytoestrogens in the composition.

Granger et al. do not teach the storage of first composition comprising retinoid, and second composition comprising, glycyrrhetic acid, and phytoestrogens, in separate compartments joined together.

Gorbach teaches that phytoestrogens such as genistein, daidzein, glycitin, equol, formononetin are useful for treating wrinkles, aging skin etc. Phytoestrogens are present in an amount of 1 and 40 mg per gram of base. See abstract; page 2, lines 7-15; column 6, claims 1-4.

Liu et al. teach that retinoids such as retinal, retinyl ester in skin care compositions are unstable due to oxidation or isomerization to non-efficacious chemical forms with the result that the amount of retinoid actually present to provide the beneficial effects is reduced in a short period of time. See column 2, lines 40-55. It is further taught that several stable compositions for skin care are supplied in two bottles (separating retinoids from other cosmetic ingredients), portions of which are mixed together just prior to use. See column 2, lines 54-62.

Suares et al. teaches a method for a skin treatment regime and product that includes a first composition containing at least one active and functioning to impart a benefit to skin, and a second composition that includes a second different active and imparts a benefit to skin (see abstract, in particular). Suares et al. teaches that the first and second compositions are stored in respective separate containers, which are joined together (see abstract and column 2, lines 1-14, in particular.) Suares et al. teaches that the two compositions are kept separate because single formulations often compromise the performance of the severally combined actives (see column 1, lines 15-25, in particular.) Accordingly, Suares et al. teachings provide a first composition in a first compartment, and a second composition in a second compartment, where the first and second compartments are joined together, as recited in claim 1. Those formulation taught by Suares et al. employ retinoid compositions useful for anti-wrinkle, and sunscreen dermal applications. See column 3, Table I; column 4, lines 59-64; TABLE III, column 8, and TABLE IV, column 9. Suares also teach a first composition,

containing retinoid, and a second composition containing genistein, which are joined together. See TABLE III, column 8, and TABLE IV, column 9.

From the teachings of Gorbach, it would have been obvious to a person of ordinary skill in the art at the time of invention to add phytoestrogens such as genistein, diadzein to the compositions of Granger et al. since phytoestrogens are used to treat skin conditions such as wrinkled, photodamaged skin. It is generally considered a *prima facie* obvious to combine compounds each of which are taught by the prior art to be useful for the same purpose, in order to form a composition, which is used for the very same purpose. The idea of combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Granger, and Gorbach the instant claims contain compounds retinoids, glycyrrhetic acid, and phytoestrogens used for improvement of skin appearance. *In re kirkhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ a two compartment system for separately storing retinol or retinyl ester in a first composition, and retinoid boosters such as glycyrrhetic acid, linoleic acid, phosphatidylcholine and phytoestrogens in the second composition.

One having ordinary skill in the art would have been motivated at the time of invention to employ two compartments to separately store retinol or retinyl ester, and retinoid booster glycyrrhetic acid and phytoestrogens because Liu et al. teach that the skin compositions containing retinol or retinyl esters are unstable as they quickly lose their activity by, for example, either being oxidized or isomerizing to non-efficacious

chemical forms and chemical degradation. Moreover, several known stable skin care compositions containing retinol or retinyl esters are known to be supplied in two bottles or two portions to separate retinoids from other cosmetic ingredients to keep retinoids from chemical reactions with other ingredients (the first and second compositions are known to be stored in respectively separate compartments or containers, being joined together) based on the teachings of Liu. Therefore, one of ordinary skill in the art would have found it obvious to employ two compartments for separately storing retinol or retinyl ester in a first composition and retinoid boosters, phytoestrogens in the second composition to keep retinol or retinyl ester from reacting with retinoid boosters and phytoestrogens in order to preserve the stability of retinoids in the compositions to avoid chemical degradation, and keep retinoids from chemical reactions with other ingredients to avoid chemical degradation.

Further, Soares et al. also employ a dual container system for multi composition use, and teaches the desirability of providing the two compartment product to maximize the effectiveness of the separate compositions, and teaches retinoids in one of the compositions. Those formulations taught by Soares et al employ retinoic acid in one compositions and phytoestrogen, genistein in another composition which are joined together useful for dermal application (see column 4, line 24). Possessing this teaching the skilled artisan would have been further motivated to employ the dual container dermal administration system for the application of dermal medicaments, while enjoying those benefits inherently present in the compositions. The skilled artisan would have seen the separate packaging teachings Soares et al. useful for individual application of

dermal retinoic acid compositions, and the administration of these compositions dermally and individually as residing in the skilled artisan purview.

Thus, the teachings of Liu in particular and Soares et al. have clearly provided the motivation to employ the separate compartments herein.

Regarding the recitation "wherein the booster potentiates the action of the retinoid and inhibits degradation of retinoic acid", and the recitation that the components of the second composition act as "boosting the first benefit", as recited in the claims, it is noted that the boosting activity and inhibition of degradation of retinoic acid by a compound are properties thereof. It is pointed out that a product and its properties are inseparable. In re Papesch, 315 F.2d 381,137 USPQ 43 (CCPA 1963). Accordingly, the composition rendered obvious by the combined references would, absent evidence to the contrary, meet the limitations pertaining to the retinoid boosting activity of the compound, and inhibition of degradation of retinoic acid by the compound used therein.

Further, the recitation "the first composition and second composition only come in contact after being applied simultaneoulsy or consecutively", is considered a use of the composition and does not get patentable weight in composition claims. The teaching of Granger et al., Gorbach, in view of Liu et al., and Soares et al. obviously teach the claimed composition, thus the use is not given patentable weight.

Claims 1, 2, 5, 6, and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Granger et al. (US 5,723,139, PTO-892), Gorbach (WO 98/56373,

PTO-892), and Meybeck (FR 2 777 179; PTO-892) in view of Liu et al. (5,976,555, PTO-892), and Soares et al. (US 5,914,116, PTO-1449 of record).

Granger et al., Gorbach, Liu et al., Soares et al. are as discussed above.

Granger et al. do not teach the presence of phosphatidylcholine in the composition.

Granger et al. do not teach the storage of first composition comprising retinoid, and second composition comprising retinoid boosters, phytoestrogens, in separate compartments joined together.

Meybeck et al. teach cosmetic and skin care compositions comprising retinoid, retinoid boosters such as 22-29 % of phosphatidyl choline, 0.1 % of glycyrrhetic acid. These compositions can be used for treating skin conditions such as acne, aged skin, dry skin, etc. See page 3, lines 24-27; pages 8-9, Examples 1-2.; page 13, Example 11.

From the teachings of Meybeck et al., it would have been obvious to a person of ordinary skill in the art at the time of invention to add retinoid booster, phosphatidyl choline to the compositions of the Granger et al., since phosphatidyl choline is used to treat skin conditions such as dry skin, aged skin, acne etc. From the teachings of Gorbach, it would have been obvious to a person of ordinary skill in the art at the time of invention to add phytoestrogen such as genistein to the compositions of Granger et al. since phytoestrogens are used to treat skin conditions such as wrinkled, aged, and photodamaged skin. It is generally considered a prima facie obvious to combine compounds each of which are taught by the prior art to be useful for the same purpose, in order to form a composition, which is used for the very same purpose. The idea of

combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Granger, Gorbach, and Meybeck et al., the instant claims contain compounds such as retinoids, phosphatidyl choline, glycyrrhetic acid and phytoestrogens used for improvement of skin appearance. *In re kirkhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ a two compartment system for separately storing retinol or retinyl ester in a first composition, and retinoid boosters such as glycyrrhetic acid, linoleic acid, phosphatidylcholine and phytoestrogens in the second composition.

One having ordinary skill in the art would have been motivated at the time of invention to employ two compartments to separately store retinol or retinyl ester, and retinoid booster glycyrrhetic acid and phytoestrogens because Liu et al. teach that the skin compositions containing retinol or retinyl esters are unstable as they quickly lose their activity by, for example, either being oxidized or isomerizing to non-efficacious chemical forms and chemical degradation. Moreover, several known stable skin care compositions containing retinol or retinyl esters are known to be supplied in two bottles or two portions to separate retinoids from other cosmetic ingredients to keep retinoids from chemical reactions with other ingredients (the first and second compositions are known to be stored in respectively separate compartments or containers, being joined together). Therefore, one of ordinary skill in the art would have found it obvious to employ two compartments for separately storing retinol or retinyl ester in a first composition and retinoid boosters, phytoestrogens in the second composition to keep

retinol or retinyl ester from reacting with retinoid boosters and phytoestrogens in order to preserve the stability of retinoids in the compositions to avoid chemical degradation, and keep retinoids from chemical reactions with other ingredients to avoid chemical degradation.

Further, Soares et al. also employ a dual container system for multi composition use, and teaches the desirability of providing the two compartment product to maximize the effectiveness of the separate compositions, and teaches retinoids in one of the compositions. Those formulations taught by Soares et al employ retinoic acid in one compositions, and phytoestrogen, genistein in another composition which are joined together useful for dermal application (see column 4, line 24). Possessing this teaching the skilled artisan would have been further motivated to employ the dual container dermal administration system for the application of dermal medicaments, while enjoying those benefits inherent in sequential application as set forth in Soares et al. claim 1. The skilled artisan would have seen the separate packaging teachings Soares et al. useful for individual application of dermal retinoic acid compositions, and the administration of these compositions dermally and individually as residing in the skilled artisan purview.

Thus, the teachings of Liu in particular and Soares et al. have clearly provided the motivation to employ the separate compartments herein.

Regarding the recitation "wherein the booster potentiates the action of the retinoid and inhibits degradation of retinoic acid", and the recitation that the components of the second composition act as "boosting the first benefit", as recited in the claims, it is noted that the boosting activity and inhibition of degradation of retinoic acid by a

compound are properties thereof. It is pointed out that a product and its properties are inseparable. In re Papesch, 315 F.2d 381,137 USPQ 43 (CCPA 1963). Accordingly, the composition rendered obvious by the combined references would, absent evidence to the contrary, meet the limitations pertaining to the retinoid boosting activity of the compound, and inhibition of degradation of retinoic acid by the compound used therein.

Further, the recitation "the first composition and second composition only come in contact after being applied simultaneoulsy or consecutively", is considered a use of the composition and does not get patentable weight in composition claims. The teaching of Granger et al., Gorbach, in view of Liu et al., and Soares et al. obviously teach the claimed composition, thus the use is not given patentable weight.

Response to Arguments

Applicant's arguments have been considered, but not found persuasive as discussed above, and those found below.

Applicant argues that "the references fail to even remotely teach, suggest or disclose the need to separate phytoestrogens from retinoids. The present invention, again, is directed to two separate compositions with one intended to boost the benefit of the other after application. According to the present invention, the two compositions are intended to be applied simultaneously or consecutively, but are kept separately for stability reasons until application." These arguments have been considered, but not found persuasive. Granger et al. teach a skin conditioning composition comprising a compound selected from retinal or retinyl ester in an amount from about 0.001 % to

about 10 %, in combination with a retinoid booster, polycyclic triterpene carboxylic acid, glycyrrhetic acid in an amount from about 0.0001 % to about 50%. See column 1, line 42-column 3, line 39. It is further taught that the combination of retinal or a retinyl ester with a polycyclic triterpene carboxylic acid, glycyrrhetic results in synergistic inhibition of keratinocyte differentiation. From the teachings of Gorbach, it would have been obvious to a person of ordinary skill in the art at the time of invention to employ phytoestrogens such as genistein, diadzein in combination with retinoids, and glycyrrhetic taught by Granger for treating wrinkles. It is generally considered a prima facie obvious to combine compounds each of which are taught by the prior art to be useful for the same purpose, in order to form a composition, which is used for the very same purpose. Soares et al. teaches that skin care compositions are kept separate because single formulations often compromise the performance of the severally combined actives see column 1, lines 15-25, in particular. Further, Soares et al. teaches the employment of a dual container system that allows two compositions to be separated from one another, to maximize the effectiveness of the separate compositions, while also allowing for application of both compositions from a single product, and also provides an example wherein one composition contains retinoid, and a second composition contains genistein. Thus, it is considered that Soares et al. teaches that the compositions are isolated in each compartment so that the actives in each composition will not compromise the performance of one another, and thus teaches compartments in which the compositions are not degraded by each other and do not come in contact when being stored, as recited in claim 1. Liu et al. teaches that retinol or retinyl esters are

known to be supplied in two bottles or two portions to separate retinoids from other cosmetic ingredients to keep retinoids from chemical reactions with other ingredients. Accordingly, from the teachings of Soares et al., and Liu there is clear motivation to provide a composition comprising retinoid in a first compartment, and a second composition comprising retinoid booster and phytoestrogen in a second compartment, where the first and second compartments are joined together i.e retinoids are kept separate from other actives for stability reasons. The references '139, '373 render the claimed invention obvious in combination with '555, '116. Particularly, '116 teaches a stable skin care product that has two compositions that are isolated from each other in different compartments prior to use in the abstract and column 2; lines 1-14. More particularly, '116 teaches that the two compositions are kept separate because single formulation often compromise the performance of the severally combined actives (see abstract and column 2; lines 1-14).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 5-6, and 9-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6565864, in view of Granger et al. (US 5,723,139). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to substantially overlapping skin care product containing a first composition comprising retinoid, and a second composition comprising retinoid booster. "139 does not expressly claim the employment of retinoid booster such as glycyrrhetic acid in the second compositions therein. Granger et al. teach a skin conditioning composition comprising a compound selected from retinal or retinyl ester in an amount from about 0.001 % to about 10 %, in combination with a retinoid booster, polycyclic triterpene carboxylic acid, glycyrrhetic acid in an amount from about 0.0001 % to about 50%. Thus, the employment of retinoid booster such as glycyrrhetic acid would have been obvious in view of the secondary reference. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ glycyrrhetic acid in the second composition. It is prima facie obvious to combine two agents, glycyrrhetic acid, and phytoestrogens as in instant claims, which are known to be useful as skin conditioning agents individually into a single composition useful for the very same purpose. See *In re Kerkhoven* 205 USPQ 1069. Therefore, the instant claims 1-2, 5-6, 9-10 are seen to be obvious over claims 1-2 of the patent '139.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit :1617*

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617

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